



U.S. Environmental Protection Agency
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
Room S4900, One Potomac Yard
2777 Crystal Drive Arlington, VA 22202

Attention:

Emily Schmid
Registration Division
Herbicide Branch

**Subject: Submission of application for new product registration under
PRIA category R320: M1768 Herbicide; Alternate Brand Name:
XtendiMax® With VaporGrip® Technology; EPA Reg. No. 264-XXX**

Dear Emily Schmid,

Bayer Crop Science (EPA Company Number 264) herein submits an application and proposed label for a new product registration for M1768 Herbicide (XtendiMax® With VaporGrip® Technology). As you are aware, the prior M1768 Herbicide registration (EPA Reg. No. 524-617) was the subject of EPA's June 8, 2020 cancellation order, allowing continued use of existing stocks of the herbicide after a decision by the U.S. Court of Appeals for the Ninth Circuit on June 3. As such, EPA's approval of this label would create a new M1768 Herbicide registration, thereby necessitating a new application for registration under PRIA. We are duly submitting a tentative label for this product under the proper PRIA category R320, "New product; new physical form; requires data review in science divisions."). Part of the corresponding fee of \$13,888 for PRIA 4 category R320 was paid through Pay.gov (\$1662; Tracking IDs: 26PA375S, Agency Tracking IDs: 76011710978), and the remainder of the fee (\$12,226) should be covered by PRIA credits to Bayer CropScience (EPA Payment Code A264954315B).

Because the prior registration would have expired by its own terms later this year and EPA was already considering renewal, a substantial number of relevant submissions have already been provided to the agency (and, we understand, were already under consideration). For example, MRIDs 51017501-51017511,

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July 02, 2020

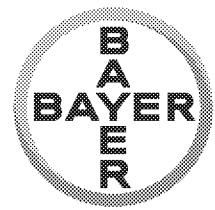
Steven T. Callen, Ph.D.

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MRID 51068201, MRID 51091001, and MRIDs 51134101-51134105. Additionally, in the coming week, we anticipate proposing specific additional revisions to the tentative label, including changes relevant to concerns regarding drift and volatility. We also anticipate ongoing discussions with the agency regarding the underlying scientific bases for our proposed label revisions and related issues.

Data owned by Bayer in support of this registration that have been previously submitted to EPA, including data submitted prior to the November 1, 2018 registration decision for M1768 Herbicide, in 2019 and 2020 to fulfill the 2018 Terms and Conditions of registration for M1768 Herbicide, and in 2020 to support the volatility-reducing agent MON 51817 (alternate brand name: VaporGrip® Xtra Agent) as a tank mix requirement for all M1768 Herbicide applications, are provided in the 40 CFR Part 158 Data Reference List included in this submission. Data previously cited but not owned by Bayer are covered under an existing Letter of Access from BASF, and no additional data compensation is required.

Given the recent history regarding this registration, we fully anticipate continued dialogue regarding restrictive provisions on the label, additional studies, and other information assembled since the 2018 registration. Indeed, we anticipate summarizing this information in an upcoming submission to assist EPA in reviewing the multiple submissions previously made to the agency. In the interim, should you require any additional information or have any questions or concerns regarding this submission, please contact me (contact information on page 1) or George Sabbagh in our Washington D.C. office at (913) 231-6291 or george.sabbagh@bayer.com.

Sincerely,

Bayer U.S. – Crop Science

A handwritten signature in black ink, appearing to read "Steven T. Callen".

Steven T. Callen, Ph.D.
Federal Regulatory Manager